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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CARL E. HANSON

Serial No.: 08/903,677

Filed: July 31, 1997

For: METHOD OF TREATING ANGINA

Group Art Unit: 3738

Examiner: Dinh Nguyen

RESPONSE

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action mailed September 1 and September 17, 1998, applicant submits the following remarks.

Claims 1-17 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not enabled in the specification. Applicants respectfully submit that this rejection cannot be sustained.

In making the enablement rejection, the Examiner has taken the position that the applicant "has given no proof that the method as claimed would prevent 'chest pain'". Applicant strongly disagrees with this position. The specification is replete with descriptions of how chest pain is alleviated by taking lime juice into the body. Indeed, there are a number of working examples where the applicant personally demonstrated this effect. The record clearly displays evidence of enablement. What the record lacks, however, is evidence that the invention would not have been enabled. The Examiner is aware that the United States Patent and Trademark Office (USPTO) has the burden of establishing why the specification does not enable the claimed invention. *In re Angstadt,* 190 USPQ 214, 219 (CCPA 1976). In so doing, the USPTO must back up any assertions of non-enablement with acceptable evidence or reasoning that shows the contested

position to be inaccurate. *In re Marzocchi,* 169 USPQ 367 (CCPA 1971) ("In any event, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.")

The present invention is directed to alleviating or eliminating cardiac chest pain by taking lime juice into the body shortly after receiving the pain. The applicant has demonstrated that this consistently occurs. After performing numerous experiments, the applicant was so comfortable with the results that he replaced his nitroglycerin prescription with the use of lime juice. Considering the risks that are entailed by not taking a prescription medicine for a heart condition, the results the applicant experienced were quite astonishing. Applicant does not simply attest that he has received "beneficial effects" from drinking a "large quantity" of lime juice. The Examiner's reference to a placebo effect, and that the result may have stemmed from vitamin C, are purely speculative. The Examiner's remarks concerning psychological effects are clearly not supported by the record when the relief experienced is immediate and is encountered by taking less than a teaspoon of frozen concentrated lime aid. As the Examiner is aware, the disclosed utility must be accepted as being accurate when the record is devoid of any authority in variance to that utility. *In re Bundy,* 209 USPQ 48, 51 (CCPA 1981) ("The PTO must had adequate support for its challenge to the applicant's statements as to utility. Only then does the burden shift to appellant to provide rebuttal evidence."); *In re Gazave,* 154 USPQ 92 (CCPA 1967) ("[A]ppellant's assertions of usefulness in his specification appear to us to be believable on their face and straightforward, at least in the absence of reason or authority in variance.").

In regard to the Examiner's comments on a lack of proof for the "active ingredients", applicant submits that such proof is not necessary. Applicant has clearly demonstrated how to make and use the invention claimed in the application. This is sufficient to satisfy the enablement requirement. The same holds true for the Examiner's remarks concerning an "effective amount". The fact that a mental determination may be needed to determine the amount of a compound administered is not a bar to patentability. *In re Campbell,* 99 USPQ 51 (Brd of Appls 1952) ("After careful consideration of the Examiner's remarks and the above disclosure, we are

constrained to hold that in our opinion the determination of the proper dosage would be within the skill of the physician."). Use of the term "effective amount" does not implicate the enablement requirement unless evidence can be presented showing that undue experimentation would be involved. *In re Halleck,* 164 USPQ 647, 649 (1970) ("Those skilled in the art will be able to determine from the written disclosure and its examples what an effective amount for growth stimulation is. Granted that the proportions may vary for a specific agent and specific animal at a particular stage of growth, it does not appear from the facts of record that determination of such amounts would be *beyond the skill of the art nor that it would involve undue experimentation to ascertain them.*")

Claims 1-17 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons given in regard to lack of enablement for the terms "active ingredients" and "effective amount". Applicant has reviewed these remarks but found nothing in that paragraph which explains why the claim is indefinite. It is incumbent upon the Examiner to give reasons that explain why the *claim is imprecise.* The focus of the inquiry is on the claim language. It is not proper to refer to an "absence of proof" in making such a rejection. *In re Ehrreich,* 200 USPQ 504, 507-08 (CCPA 1979) ("The second paragraph of Section 112 pertains *only* to claims....Agreement, or lack thereof, between the claims and the specification is properly considered only with respect to the first paragraph of § 112; it is irrelevant to compliance with the second paragraph of that section.")

Claims 1-7 have been rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a), as obvious over Singh et al., Langtry et al., Reimersma et al., or Dapcich-Miura et al. Applicant respectfully submits that these rejections cannot be sustained.

None of the documents that have been cited by the Examiner disclose the intake of lime juice by a person shortly after experiencing chest pain. Without such a disclosure, the claims clearly are not anticipated under the terms of 35 U.S.C. § 102(b). As the Examiner is aware, a reference relied upon in making an anticipation rejection must disclose all of the elements of the claimed invention. This situation clearly does not exist in regard to any of the references cited by the Examiner.

In regard to the obviousness rejection, none of the documents teaches or suggests using lime juice to alleviate chest pain associated with a cardiac condition. Singh discloses a placebo controlled trial where a cocktail of vitamin A, vitamin C, vitamin E, and beta carotene are given to patients suspected to have acute myocardial infarction. This document does not suggest that lime juice can be taken to counter the effects of angina pectoris. Lacking such a teaching or suggestion, this reference clearly would not have led a person of ordinary skill to the present invention.

Langtry et al. discloses how a nisoldipine core-coat controls systems of angina and approves exercised-induced signs of ischaemia in patients with stable angina. This document does not teach or suggest the beneficial effects of taking lime juice after experiencing cardiac chest pain. To the extent that the Examiner believes that such a connection would be made based on a relation to vitamin C, this reference recommends against the use of grapefruit juice when taking nisoldipine therapy. If anything, this document teaches away from applicant's invention.

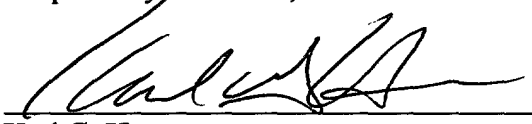
Reimersma et al. examines the risk between angina pectoris and plasma concentrations of vitamins A, C, and E and carotene. Nowhere does this document teach or suggest taking lime juice into the body to alleviate cardiac chest pain. The document merely discusses the relationship between concentrations of these vitamins in plasma to persons who exhibit angina.

Dapcich-Miura et al. also would not have rendered applicant's invention obvious. This document describes how an experimentee, namely Mr. A, could be induced into increasing adherence to a complex medical regimen. Using certain intervention, Mr. A began walking, drinking orange juice, and taking all of his prescribed medication. The document merely describes a regimen that can be employed to increase medication use to alleviate angina pain. Although the reference mentions another fruit juice, namely orange juice, it in no way suggests the use of lime juice to immediately alleviate chest pain associated with a cardiac condition. Indeed the applicant has drank orange juice after experiencing an angina attack but detected no relief from such a product. Lacking any suggestion of using lime juice or the beneficial effects that can be immediately achieved through such use by a person with angina, this document clearly does not teach or suggest the present invention.

In view of the failure of all of the references cited by the Examiner to teach or suggest the use of lime juice shortly after experiencing cardiac chest pain, these documents surely would not have made applicant's invention obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103. Accordingly, applicant urges the Examiner to withdraw this rejection and allow the application at an early date.

Dated this 17th day of December, 1998.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on the date noted below.

Karl G. Hanson

Dated: December 17, 1998